

Reply to Office Action dated February 20, 2007

REMARKS

Claims 1-21, 29-45 and 54-59 are pending for examination with claims 1, 29, 37 and 54 being independent claims; claims 8-13 have been withdrawn. No new matter has been added.

Rejections Under 35 U.S.C. §103

Claims 1-7, 14-17, 20, 29-35, 37-44, and 54-58

Claims 1-7, 14-17, 20, 29-35, 37-44, and 54-58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meier (U.S. Patent No. 3,416,524) in view of Ory et al. (U.S. Patent No. 6,264,702). Applicant respectfully traverses these rejections.

Independent claims 1, 29, 37 and 54 are each directed to an *implantable prosthesis* including, *inter alia*, a layer of repair fabric and a barrier layer configured to inhibit the formation of adhesions between at least a portion of a surface of the repair fabric and adjacent tissue and organs. The layer of repair fabric has an outer peripheral edge or an outer margin with an outer peripheral edge.

Claim 1 recites that the prosthesis also includes a peripheral barrier that inhibits the formation of adhesions with adjacent tissue and organs thereto and is maintained across the entire thickness of a portion of the outer peripheral edge of the repair fabric.

Claims 29 and 54 recite that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

Claim 37 recites that the outer margin of the layer of repair fabric has been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs.

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15 which are joined by needled resin fibers 16 using a needling and heat fusion process. The cellulosic layer has moisture absorption properties while the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

In the office action, the examiner acknowledges that Meier fails to disclose that the frame 12 inhibits the formation of adhesions with tissue or organs thereto. (Office Action, page 2). In an effort to address this deficiency, the examiner looks to Ory which discloses an implantable

prosthesis including a layer of repair fabric 4 and an absorbable barrier layer 3. Ory indicates that the barrier layer projects beyond the fabric layer in such a way as to protect the prosthesis from visceral contacts. (Col. 4, lines 26-30).

In the office action, the examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the frame of Meier to comprise a material that is adhesion resistant, in view of Ory, to inhibit the formation of adhesions with adjacent organs after implantation. Applicant respectfully disagrees.

One of ordinary skill in the art would not have been led to modify Meier in view of Ory.

First, the alleged motivation for modifying the Meier frame finds no support in the record. In particular, as discussed above, Meier is directed to a ***surgical dressing*** which is used, as one of ordinary skill in the art would readily appreciate, to cover a surface wound. Meier is ***not*** an implantable prosthesis that would be implanted adjacent internal tissue or organs. Consequently, there simply would have been no reason for one of skill in the art to even contemplate, let alone to have been led, to modify the Meier frame so as to inhibit the formation of adhesions with adjacent organs after implantation as contended in the office action.

Second, Ory does not teach or suggest an implantable prosthesis that is configured to inhibit adhesions to the peripheral edge of the repair fabric. In this regard, although the barrier layer of the Ory prosthesis projects beyond the repair fabric, there is no teaching or suggestion that the layer is maintained across any portion of the fabric edge so as to protect the peripheral edge from forming adhesions with adjacent tissue and organs as asserted in the office action. Ory also expresses no desire to prevent the formation of adhesions to the outer peripheral edge of the fabric. Rather, one of ordinary skill in the art would appreciate from Fig. 1 that the outer peripheral edge of the Ory fabric 2 is exposed and would be subjected to tissue ingrowth and adhesion formation from at least the mesh side of the prosthesis.

Third, as indicated above, Meier employs the frame to stabilize the edges of the cellulosic layer and the resin fiber layer. In this regard, Meier discloses that the frame provides freedom from fraying, loose fibers and delamination which were purported to be undesirable problems of prior surgical dressings. (Col. 1, lines 21-30 and col. 2, lines 51-56). As indicated above, Ory employs an absorbable film as the barrier layer. Thus, any modification of the Meier frame to employ an adhesion resistant material in view of Ory, as contended in the office action, would

Reply to Office Action dated February 20, 2007

involve the use of an absorbable material for the frame. However, there is no teaching or suggestion that the use of an absorbable material would be desirable for the Meier frame. Rather, one of ordinary skill in the art would have appreciated that the use of an absorbable material for the Meier frame would result in an absorbable frame that may potentially lead to fraying, loose fibers and delamination, in contrast to the teaching of Meier.

In view of the foregoing, Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the office action. Meier and Ory do not provide any teaching or suggestion that would have led one of ordinary skill in the art to modify the Meier frame in the manner suggested in the office action. Applicant respectfully submits that any assertion that it would have been obvious to modify Meier in view of Ory would appear to be the result of improper hindsight reconstruction in view of Applicant's claimed invention. Accordingly, the rejection of independent claims 1, 29, 37 and 54 under §103 in view of Meier and Ory is improper and should be withdrawn.

Claims 2-7, 14-17, 20, claims 30-35, claims 38-44, and claims 55-58 depend respectively from claims 1, 29, 37 and 54 and are patentable for at least the same reasons.

The claims patentably distinguish over Meier in view of Ory.

For the sake of argument only, even were one of ordinary skill in the art to have somehow been led to modify the Meier frame to be formed of an adhesion resistant material in view of Ory, the claims patentably distinguish over the references.

As indicated above, each of the claims is directed to an implantable prosthesis. In contrast, Meier is directed to a surgical dressing, not an implantable prosthesis as contended in the office action. Meier provides no teaching or suggestion that the surgical dressing can be or is even capable of being used as an implantable prosthesis. Thus, independent claims 1, 29, 37 and 54 patentably distinguish over the modification of Meier in view of Ory such that the rejection of these claims under §103 should be withdrawn for at least this additional reason.

In the office action, the examiner contends that the frame 12, the cellulosic layer 14 and the resin fiber layer 15 are shown tapering towards the outer edge of the pad as shown in Fig. 4. Without acceding to this characterization of Meier, Applicant respectfully submits that Meier does not teach or suggest a layer of repair fabric with an outer peripheral edge having a thickness that is less than the thickness of the inner body of the fabric as recited in claim 29. Rather, as

Reply to Office Action dated February 20, 2007

shown in Fig. 4, the cellulosic layer 14, which the examiner contends is the fabric layer, appears to have a constant thickness. Thus, claim 29 patentably distinguishes over Meier and Ory such that the rejection under §103 should be withdrawn for at least this additional reason.

In the office action, the examiner contends that Meier discloses a peripheral barrier that may be melted and resolidified. Without acceding to this characterization of Meier, Applicant respectfully submits that Meier does not teach or suggest melting and resolidifying the outer margin of the layer of repair fabric to render the entire thickness of the outer peripheral edge of the repair fabric resistant to the formation of adhesions with tissue and organs as recited in claim 37. Rather, Meier indicates that the frame may be softened so that it tends to merge with adjacent loose fibers or frayed edges of the pad. (Col. 3, lines 10-16). Thus, claim 37 patentably distinguishes over Meier and Ory such that the rejection under §103 should be withdrawn for at least this additional reason.

Claim 54 recites that the entire thickness of the outer peripheral edge of the layer of repair fabric is adapted to inhibit the formation of adhesions thereto, and the outer margin of the layer of repair fabric is reinforced to form a bite region that is spaced inward of the outer peripheral edge for securing the prosthesis along the outer margin. The office action is silent as to the teachings of Meier and Ory related to this combination of features. Consequently, withdrawal of the rejection of claim 54 under §103 is requested for this additional reason.

Claims 2-7, 14-17, 20, claims 30-35, claims 38-44, and claims 55-58 depend respectively from claims 1, 29, 37 and 54 and are patentable for at least the same additional reasons.

Claims 18, 19, 21, 36, 45 and 59

Claims 18, 19, 21, 36, 45 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meier in view of Ory and further in view of Sharber (U.S. Patent No. 6,075,180).

Without acceding to the propriety of the reference combination suggested by the Examiner, claims 18-21, claim 36, claim 45 and claim 59 depend respectively from claims 1, 29, 37 and 54, and are patentable for at least the same reasons set forth above. Accordingly, the rejection of claims 18-21, 36, 45 and 59 under §103 should be withdrawn.

Reply to Office Action dated February 20, 2007

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: James M. Hanifin, Jr.
James M. Hanifin, Jr., Reg. No. 39,213
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No.: D0188.70125US00

Date: 6/20/07